In re of Appln. No. 09/155,676

REMARKS

Claims 13-16, 20-22, 30, 43-50, 52-60, and 62-71, 73-75 and 77-79 presently appear in this application with claims 52-54 and 65-68 indicated as being allowed. The remaining claims have been rejected. The official action of June 27, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to cDNA sequences that encode polypeptides that bind to TRAF2 and inhibit or increase activity of NF-κB as well as the polypeptides encoded by those DNA sequences. Preferably, the polypeptide is NIK. The invention also relates to antibodies, methods of identification and screening, and anti-sense DNA.

The examiner states that the amendments to the claims filed on April 15, 2003, do not comply with the requirements of 37 CFR 1.121(c) because the status of cancelled claim 61 was omitted and because changes were made in claims 45-48 and 64 without indicating that these claims were currently amended.

The errors in the amendment of April 15, 2003, noted by the examiner, are regretted. The set of claims attached hereto indicates that claim 61 has been previously cancelled. Furthermore, claims 45-48 and 64 are being amended hereby in order to place them back into the same language that they had been in, in the amendment of September 10, 2001. Due to an inadvertant error, the language prior to September 10, 2001, was used when

these claims were set forth in the amendment of April 15, 2003. The present amendment to these claims merely returns them to the form that they appeared as of October 10, 2001. It should be noted, however, that a minor additional change has been made to claim 48, so that the language of paragraph (a) will track the language of the preamble, in the same manner as is done in claim 49. It is believed that the format of the present amendment fully complies with the revised amendment practice of 37 CFR 1.121.

Claims 13-16, 20-22, 30, 43-50, 54-60, 63-65 and 69-79 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The examiner states that the amendment of April 15, 2003, amends claim 69 to recite in part (c) "an amino acid sequence of a fragment of (a) or (b)". The examiner states that the specification does not describe with reasonable clarity, deliberateness and precision wherein the "fragments" recited in claim 69 encompass "fragments" of an "analog".

In order to obviate this rejection, claim 69 has now been amended to delete reference to fragments of the analogs of (b). As this is the only portion of claim 69 that the examiner has found objectionable, it is believed that claim 69 and all those claims dependent therefrom now fully comply with the first paragraph of 35 USC 112.

The examiner states that claim 45 is drawn to a method for identifying and producing a ligand capable of either inhibiting or decreasing the cellular activity that is changed or

mediated by TRAF2 and that claim 48 recites a method for identifying and producing a molecule capable of directly or indirectly either inhibiting or decreasing the cellular activity that is changed or mediated by NIK. The examiner states that the specification as filed provides no indication of what specific polypeptides are used in the claimed methods, particularly with respect to amino acid substitutions, deletions, insertions or modifications. The examiner states that further experimentation is necessary to isolate the compounds used in the instant claims. This part of the rejection is respectfully traversed.

First of all, this is the first time in the lengthy prosecution of this case that the examiner has specifically rejected independent claims 45 and 48 on this grounds. Previously, they have only been included with the rejections of the other claims. This is effectively a new ground of rejection of claims that have not been amended in the previous response and therefore the finality of the present rejection is inappropriate. **Reconsideration and withdrawal of the finality of the official action of June 27, 2003, for this reason is therefore respectfully urged.**

With respect to the merits of this rejection, it should be noted that claim 45 specifies that step (a) is a screening step, which includes screening for a ligand capable of binding to a very specific polypeptide. The polypeptide used in the test is one defined as having at least the amino acid residues 222-501 of TRAF2. It is not necessary to know in advance what ligands will

bind, as the purpose of the claim is to find what ligands bind. Any and all ligands can be used in the screen. It need not be expected in advance that any such ligand will bind. Screening steps typically involve a huge variety of potential binding partners. It is the step of the claim itself that determines whether or not any of these bind. Only when, and if, something binds to the portion of TRAF2 having the amino acid residues 222-501 of TRAF2, does one identify that ligand in step (b) and characterize it and then produce it in step (c). The ligand that binds is not claimed, only the method of screening for and identifying anything that may bind. There is no requirement that anything will be found in the screening step. No experimentation is involved whatsoever; the experimentation is in the step of the claim. The claim can be practiced without knowing anything about what the test substances are that are passed through the screening step. There is no requirement to know in advance what the properties of the materials are being fed to the screen. The same logic also applies to the screen of claim 48. In another case involving the laboratory of the present inventor, the Board reversed a rejection of a screening claim such as this. A copy of this decision is attached hereto. While this decision is not precedential, its logic is applicable to the present case. Accordingly, reconsideration and withdrawal of this part of the rejection is also respectfully urged.

Claims 45-48 and 64 have been rejected under 35 USC 112, second paragraph as being indefinite in using the term "a ligand capable of either inhibiting or decreasing".

Claims 45-48 and 64 have now been amended to correct this inadvertant error, thus obviating this rejection.

The examiner is again reminded that on February 9, 2001, two requests for interference under 37 CFR 1.607 were filed in this case requesting interferences with U.S. patents 5,843,721 and 5,844,073. Even with the present two-way test for same patentable invention that must be applied to determine whether there is an interference-in-fact, the species of the '721 and '073 patents would anticipate the corresponding generic claims of the present application, if such species claims were available to the prior art. Similarly, in the other direction, if generic claims such as claims 70 and 71 of the present application were available to the prior art, certainly the species of the '073 and '721 patents would at least be *prima facie* obvious, as the species of these patents falls within the scope of at least the relatively narrow sub-generic claims 71 and 70 of the present application. It is the relatively narrow scope of the sub-generic claims 70 and 71 that distinguishes this case from *Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash.*, 67 USPQ 2d 1161 (Fed. Cir. 2003). Certainly, each of the sequences corresponding to that of SEQ ID NO:9 in which a single alanine has been changed to a proline, or vice versa, would be envisionable and *prima facie* obvious. Thus, the two-way same invention test is met.

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All the claims now present in the case clearly define over the references of record and fully comply with 35 USC 112. Accordingly, indication of allowability of all the claims now present in the case and declaration of interferences with U.S. patents 5,583,721 and 5,844,073 are earnestly solicited.

Respectfully submitted,

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